UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories Inc.*, CIVIL ACTION NO. 06-11337-PBS	Hon. Patti Saris ***Leave to file granted on September 11, 2007***

THE UNITED STATES' SURREPLY TO ABBOTT LABORATORIES INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS

Abbott Laboratories Inc.'s ("Abbott") Reply Memorandum in Support of its Motion to Dismiss ("Reply") reiterates the various incorrect procedural arguments raised in its initial motion to dismiss; the flaws in those arguments have already been thoroughly briefed in the United States' Opposition to Abbott's Motion to Dismiss ("Opposition"). The United States submits this surreply to address a few new points raised in Abbott's Reply.

ARGUMENT

I. The Acyclovir Claims Are Properly Pled.

The United States was judicious in its selection of Abbott drugs upon which to intervene. In the United States' original Complaint, the United States intervened on 44 National Drug Codes (NDCs) covering four megaspread drugs, a very small fraction of the 1000+ NDCs included in the relator's Fourth Amended Complaint. In the United States' First Amended Complaint (FAC), the United States added two more NDCs for Acyclovir Sodium (Acyclovir). There is no real dispute among the parties that Acylcovir is a megaspread drug and that Abbott

sales personnel discussed the average wholesale prices (AWP) for this drug when marketing it to potential customers.

Abbott argues in its Reply that the Acyclovir claims in the United States' FAC should nonetheless be dismissed, arguing that (1) the justifications set forth in the United States' Opposition are somehow improper, and (2) the statutory requirements set forth in 31 U.S.C. § 3730(b) regarding dismissal of claims in a False Claims Act (FCA) case do not or should not apply in this action.

A. The Addition of Acyclovir Is Justified.

Abbott's first argument to dismiss Acyclovir from the FAC is an error-riddled and, at times, confusing *ad hominem* attack on government counsel. Abbott claims that the government presented a "demonstrably false" justification for adding Acyclovir in the FAC. Abbott claims that the government contended that it was adding Acyclovir because of "new evidence" in the form of "(1) five pages of April 8, 2007 testimony from Abbott employee Dennis Walker, and (2) an exhibit referred to in that deposition." Reply at 2. Abbott contends that the government is claiming that the evidence of its Acyclovir spread marketing is entirely new, which Abbott argues is "false, and the Government knows it."

Abbott's accusations constitute a classic straw man argument. When the United States referred to "newly obtained evidence" in the introductory section to its Opposition brief, it was broadly referring to both (1) previously concealed evidence that Abbott operated a home infusion pharmacy business that allowed Abbott to profit directly from Abbott's drug pricing

scheme,[1] and (2) *additional* evidence regarding Acyclovir. *See* Opposition at 2. Indeed, the majority of the new evidence referenced in the FAC relates to the operations of the home infusion business that directly profited off of Abbott's pricing scheme.

Regardless, this is what the government actually stated in its entirety about the addition of Acyclovir:

> The United States added this megaspread drug to its First Amended Complaint because it collected evidence showing that Abbott directly marketed the megaspread on this drug, a fact testified to by an Abbott National Account Manager during a deposition in April 2007. Exhibit 4, April 8, 2007 [sic] Deposition of Dennis Walker at 286:4-290:21. The evidence of Abbott's marketing of this drug's megaspreads as an inducement prompted the United States to add the drug to its First Amended Complaint, not Abbott's questioning of witnesses about AWP-based reimbursement generally.

Opposition at 7. In other words, Mr. Walker's deposition testimony confirming that he was discussing AWPs and the much lower contract prices for Abbott's megaspread drug Acyclovir with customers prompted the Government to reevaluate Abbott's conduct regarding the drug, which led to its inclusion in the FAC.

The United States added Acyclovir because (1) the drug is a megaspread drug, (2) at least one customer has provided information that Abbott marketed the spread on Acyclovir to it, *and* (3) through its April 5, 2007 deposition, the government obtained testimony from an Abbott employee confirming that he did discuss Acyclovir AWPs with a customer. The government never implied in its Opposition that *allegations* regarding Abbott's marketing of Acyclovir

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[1] Abbott claims that the United States' assertion that the evidence regarding its home infusion business unit was concealed is "hyperbolic." Yet, Abbott never contests the fact that it never disclosed information about this unit to either (1) the United States during its pre-intervention investigation, or (2) to the Court in connection with its first motion to dismiss. *See* Opposition at 5-6.

spreads as discussed in Mr. Walker's deposition excerpt are entirely new.[2] Rather, as expressly stated in the government's brief, the *confirmation* from Abbott's employee that he did discuss Acyclovir AWPs with customers as he marketed that drug led to the inclusion of Acyclovir in the FAC.

Abbott spends three and a half pages of its Reply attacking the two sentences previously quoted from the government's Opposition and government counsel. Much of Abbott's argument relates to an exhibit Mr. Walker is testifying about in the deposition excerpt cited in the United States' Opposition. The deposition exhibit, Exhibit 579, is a fax containing AWP and contract pricing information from which the spreads for Acyclovir can be ascertained. Abbott claims the government "falsely" stated that Exhibit 579 is "new evidence," yet the exhibit had been provided with the relator's Second Amended Complaint. Reply at 3. Abbott argues that the United States misrepresented to the Court when it first knew about this exhibit and the Acyclovir spread marketing allegations.

There is a critical flaw in Abbott's argument. First, the government never referenced Exhibit 579 in its Opposition nor claimed that it was newly obtained evidence. *See* Opposition at 7. Indeed, the government never even provided a copy of Exhibit 579 to the Court with its Opposition. The notion that the United States was citing to Exhibit 579 as the basis for its

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[2] As Abbott notes, allegations about its marketing of Acyclovir spreads had previously been identified in the relator's second amended complaint. To accept Abbott's misconduct allegation, *i.e.*, the government portraying Abbott's Acyclovir spread marketing as a previously unknown phenomenon, one would have to believe that the government thought no one would read the long unsealed portions of the relator's second amended complaint discussing Acyclovir allegations.

addition of Acyclovir in its FAC is a fiction that resides only in Abbott's Reply and nowhere in the United States' Opposition.

In short, since the United States never claimed the Acyclovir spread marketing allegations were "entirely new," Abbott's attacks on the rationales advanced in the United States' Opposition brief for adding Acyclovir to this action are without foundation or merit.

B. The FCA Requires Court and Government Written Approval to Dismiss Claims.

Section 3730(b)(1) of the FCA states that an FCA "action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." Absent both, FCA claims cannot be dismissed. Abbott contends this is an "aggressive Executive Branch reading of the FCA." Reply at 6. The government submits that its reading of the FCA is hardly aggressive; it is a plain-meaning reading of the FCA's dismissal provisions. The FCA has unique procedural requirements regarding dismissal of a claim. As one court has noted, the *qui tam* provisions of the FCA "have been crafted with particular care to maintain the primacy of the Executive Branch in prosecuting false-claims actions, even when the relator has initiated the process." *United States ex rel. Taxpayers Against Fraud* v. *General Elec. Co.*, 41 F.3d 1032, 1041 (6th Cir. 1994).

Given the plain statutory consent requirement, most of Abbott's arguments are inapposite and do not merit a response. Thus, the United States will address only those few arguments in the Reply that merit a brief response.

First, Abbott argues that 31 U.S.C. § 3730(b)(1) does not apply to the post-intervention period, citing *United States ex rel. Killingsworth v. Northrop Corp.*, 25 F. 3d 715, 721-722 (9th Cir. 1994). Numerous other courts have concluded the opposite: that government consent is

required for the dismissal of claims. *See, e.g., United States ex rel. Doyle v. Health Possibilities,* 207 F.3d 335, 338-344 (6th Cir. 2000) (declining to follow *Killingsworth* and applying a plain-meaning interpretation to 31 U.S.C. § 3730(b)(1)'s consent provisions); *Searcy v. Philips Elecs. North Am. Corp.*, 117 F.3d 154, 158-160 (5th Cir. 1997); *United States ex rel. Ridenour v. Kaiser-Hill Co., L.L.C.*, 397 F.3d 925, 931 n. 8 (10th Cir. 2005), *cert. denied*, 546 U.S. 816 (2005). *Killingsworth* does not represent the majority view on the issue of government consent to dismissal of FCA claims; the majority of the case law holds that a court should take a plain-meaning approach to applying 31 U.S.C. § 3730(b)(1) – and its government consent requirements – to the voluntary dismissal of FCA claims.

Second, Abbott claims that the government's initial declination is "tantamount to consent" to the dismissal of the Acyclovir claims, citing *Minotti v. Lensink*, 895 F. 2d 100 (2d Cir. 1990). Yet, the notice of intervention the United States did file in this case expressly stated that the United States' declination was not a consent to dismissal and consent should be obtained prior to dismissal of any claims in the future. Abbott Memorandum of Law in Support of Motion to Dismiss the United States' First Amended Complaint, Exhibit I at 3. Further, the *Minotti* case is inapposite; it only concerned whether the consent of the Attorney General is necessary when a court involuntarily dismisses a relator's complaint. *Id.* at 104. The issue in this case involves a relator's voluntary dismissal of a case, and the case law is relatively clear that 30 U.S.C. § 3730(b)(1) requires the government's written consent for a voluntary dismissal.

Finally, Abbott writes "the Government also suggests (again without authority) that 'cases analyzing intervention under Fed. R. Civ. P. 24 . . . have absolutely no relevance to intervention under the FCA.'" Reply at 7, *citing* Opposition at 18. This is another straw man

argument founded upon an incomplete restatement of what the government wrote in its Opposition. Here is the sentence in its entirety: "Abbott relies on numerous cases analyzing intervention under Fed. R. Civ. P. 24 which have absolutely no relevance to intervention under the FCA." The Government never argued that Rule 24 has no applicability to FCA cases, just that the cases Abbott cites are – and continue to be – irrelevant since they deal with inapplicable intervention issues arising in a non-FCA context.

II. Relation Back Is Not NDC or J-Code Specific.

The United States has already presented numerous arguments in its Opposition as to why relation back is not NDC or J-Code specific; the government's position is fully consistent with this Court's recent order allowing other plaintiffs in this multi-district litigation to amend their complaint to add additional NDCs related to drugs pled in their initial complaint. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 402, 404 (D. Mass. 2007) (allowing amendment of New York City and Counties' complaint to add NDCs relating to drugs pled in those plaintiffs' first complaint.)

The government would only add that the Court's drug-by-drug approach is more practical than Abbott's proposed NDC-by-NDC approach, which can lead to absurd results. The same drug can have multiple NDCs or J-Codes based on dosage or package size. For example, Dextrose Water has multiple NDCs. The first NDC for Dextrose Water that appears in the relator's original June 23, 1995 complaint is # 00074-7922-09, which is the NDC for the 1000ml dose. In the relator's August 13, 1997 Complaint, it includes for the first time the NDC for the 500ml dose of Dextrose Water, #00074-7922-03.

The product is chemically identical; the only issue is the amount of Dextrose Water in the bag. Because less Dextrose Water comes in the 500ml dose, #00074-7922-03, Abbott claims that, for relation back purposes, the drug is "different." That is far too aggressive an interpretation of Rule 15(c)'s requirement that permissible amendments must arise from the "same conduct, transaction or occurrence." The rule's relation back provision does not – and quite reasonably so – require perfect foresight into every specific claim that may arise from a fraudulent scheme. It should not be incumbent on the relator or the government to include all dosage sizes of a defendant's drug in a complaint to benefit from relation back as to that drug when additional claims for variations of the same drug are identified later during discovery.

Abbott's approach, in effect, invites plaintiffs to sue, at the outset, for all NDCs for a drug regardless of the level of information available to a plaintiff, otherwise a litigant might lose potential, unknown claims. In a fraud case, however, a plaintiff must plead claims with particularity, otherwise they are subject to dismissal. Fed R. Civ. P. 9(b). Under Abbott's view of the scope of relation back, an FCA plaintiff may be in the untenable position of having to plead all NDCs to preserve claims due to the FCA's statute of limitations, despite lacking sufficiently detailed information to survive Rule 9(b)'s requirements. A more judicious pleading approach combined with a proper reading of Rule 15(c) would allow a plaintiff to plead NDCs based on the evidence, while permitting relation back if newly discovered claims for additional NDCs arise from the same conduct, transaction or occurrence identified in the original complaint.

In sum, Abbott's NDC-by-NDC approach to relation back is neither (1) consistent with Rule 15 and this Court's previous rulings, nor (2) practical given that the same drug might have multiple NDCs based on a variety of factors.

CONCLUSION

For the reasons set forth above, the United States respectfully requests that the Court deny Abbott's motion to dismiss.

Respectfully submitted,

For the United States of America,

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

George B. Henderson, II
Assistant U.S. Attorney
John Joseph Moakley U.S. Courthouse
Suite 9200, 1 Courthouse Way
Boston, MA 02210
Phone: (617) 748-3272
Fax: (617) 748-3398

R. ALEXANDER ACOSTA
UNITED STATES ATTORNEY
SOUTHERN DISTRICT OF FLORIDA

/s/ Mark A. Lavine
Mark A. Lavine
Ana Maria Martinez
Ann St. Peter-Griffith
Special Assistant U.S. Attorneys
99 N.E. 4th Street, 3rd Floor
Miami, FL 33132
Phone: (305) 961-9003
Fax: (305) 536-4101

PETER D. KEISLER
ASSISTANT ATTORNEY GENERAL

/s/ Gejaa T. Gobena
Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca A. Ford
Gejaa T. Gobena
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
Phone: (202) 307-1088

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **THE UNITED STATES' SURREPLY TO ABBOTT LABORATORIES, INC.'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Gejaa T. Gobena
Gejaa T. Gobena

Dated: September 28, 2007